



Institutional Review Board
Initial/Resubmission Protocol Review Application
Face Page

Warning:

Submitting an application that does not meet the requirements set out in the Instruction Packet will delay your project being reviewed and approved.

1a. Protocol Submission Type (Check One): ☐ New (Initial) ☐ New (Resubmission)

1b. Protocol Title: _____

2. Starting Date: _____ 3. Ending Date: _____ 4. Total # of Subjects: _____

5. Principal Investigator (PI):

Name, Degrees: _____

Address: _____

Phone: _____

E-Mail: _____

6. TDH Contact (If different from PI):

Name, Degrees: _____

Address: _____

Phone: _____

E-Mail: _____

7. Student Investigator, provide your Thesis/Dissertation Chair:

Name: _____

University/Dept: _____

Address: _____

Phone: _____

E-Mail: _____

For Office Use Only

IRB#: _____

8. Project Funding Source (Check One):

☐ Internal (TDH)

☐ Innovation Grant (TDH)

☐ Federal Agency _____

Specific Area _____

☐ Thesis/Dissertation: University _____

Department _____

☐ University _____

☐ Private Company _____

9. Principal Investigator's Statement:

In making this application, I certify that I have read and understand the TDH IRB guidelines and procedures which are based on the Belmont Report, and that I fully intend to comply with these policies.

I further acknowledge my responsibility to report any adverse event or significant changes in the protocol.

I agree to obtain written approval for any significant changes prior to their implementation.

I will keep all records pertaining to this research for three (3) years after its completion.

Signature(s): Principal Investigator(s) or Faculty Sponsor(s)

Date Signed

10. Multi-Site Collaboration:☐ None☐ Domestic Site(s) Only[†]☐ Foreign Site(s) Only[†]☐ Domestic & Foreign Sites[†][†]See Page 3 of the Instructions Packet.**11. Other IRBs**

(Name)

(Telephone Number)

(Name)

(Telephone Number)**12. Subject Information****a. Characteristics** (Check all that apply)Age Groups ☐ 0-17 years ☐ 18-65 years ☐ 66+ yearsFetuses ☐ No ☐ YesPregnant Women ☐ No ☐ YesElderly/Aged ☐ No ☐ YesPrisoners ☐ No ☐ YesImpaired ☐ No ☐ Yes ☐ Physically ☐ Cognitively ☐ BothCompensation/Incentives ☐ No ☐ Yes (Describe) _____**b. Exclusions** (Check all that apply)☐ None☐ All Non-English Speaking☐ Male☐ Asian☐ Female☐ Black (not of Hispanic origin)☐ Pregnant Women☐ Hispanic☐ Adult☐ Native American☐ Child☐ White (not of Hispanic origin)**c. Will identifying information be collected?** ☐ Yes ☐ No**13. Additional Questions****a. Ionizing Radiation Use?** (X-rays, radioisotopes, etc.)☐ None☐ Medically indicated only (In the Synopsis of Proposal, item #4, please explain)☐ Research indicated (In the Synopsis of Proposal, item #4, please explain)**b. Investigational New Drug or Device**☐ None☐ IND☐ IDE

FDA No. _____

Name: _____

Sponsor: _____

Holder: _____

c. This project involves:

Questionnaires or surveys ?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Medical Chart review?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Biologic Sampling?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Use of biologic samples already collected?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Experimental treatment?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Withholding usual treatment?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

d. Submission of Non-English Translations:

This project involves non-English speaking participants. ☐ Yes ☐ No

Non-English languages used _____

Documents being translated _____

14. Synopsis of Proposal or Resubmission Summary (See the Instructions Packet for details)